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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 08/897,441 | 07/21/97 | FIBI | 5552.0953-04 |

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EXAMINER

CANELLA, K

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

14

DATE MAILED: 11/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/897,441

Applicant(s)

Fibl et al

Examiner

Karen Canella

Group Art Unit

1642



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 5-7, 9-12, and 14-23 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 5-7, 9-12, and 14-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Response to Amendment

1. Please note that the examiner to which your application has been assigned in the PTO has changed.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 5, 9, 14, 17 and 23 are amended. Claims 5-7, 9-12 and 14-23 are under consideration.

Claim Rejections Maintained

4. The rejection of claims 6, 7, 11, 17-21 for obviousness-type double patenting over claims 1 and 2 of USP 5,712,370 is maintained for reasons of record.

New Claim Rejections

5. Claims 5-7, 9-12 and 14-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5 and 6 recite fragments of the erythropoietin protein based on the numbering of the amino acid positions of the natural EPO. The specification teaches that natural EPO is 166 amino acids in length. However, the art teaches that human erythropoietin is 193 amino acids in length (accession number NP 000790) and rat erythropoietin is 192 amino acids in length (accession number NP 058697). For purpose of examination, the numbering of the amino acids will be considered as having an additional 27 amino acids placing residue 166 of the instant specification at residue 193, so correlation can be made to the art recognized EPO sequence.
6. Claims 5, 12 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated Sytkowski et al (USP 4,590,168). Claim 5 is drawn in part to a method of generating epitope-specific EPO antibodies comprising immunizing an animal with the peptide consisting essentially of amino acids

7-22 of erythropoietin (P4/1) and isolating the epitope-specific antibody. Further embodiments include the antibody binding to the EPO receptor and a diagnostic aid containing an EPO peptide. Sytkowski et al disclose a method of generating an antibody to the peptide APPRLINDSRVLERYLLEAKEAEKIT (USP 4,590,168, claim 12) which consists essentially of the instant P4/1 peptide. Sytkowski et al also disclose kits containing a peptide consisting of the amino acids 156-166 of erythropoietin in a diagnostic kit for performing an immunoassay. Sytkowski et al does not specifically disclose that the antibody generated against the peptide APPRLINDSRVLERYLLEAKEAEKIT bind to the EPO receptor, but consists essentially of the P4/1 peptide, therefore, antibodies directed against the APPRLINDSRVLERYLLEAKEAEKIT peptide will bind the EPO receptor

7. All other rejections and objection cited in Paper No. 12 are withdrawn.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
November 5, 2000


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